K013732

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510(k) Summary

Date: February 07, 2001

Manufacturer

Implantech Associates Inc.
2064 Eastman Ave. #101
Ventura, CA 93003

Telephone: (805) 339-9415
Fax: (805) 339-9414
Contact: Stephen Meade

Device Name Gelzone
Common or Usual Name: Gel Sheeting
Device Classification: Currently unclassified

Product Description

Gelzone is a soft, semi-occlusive, slightly adhesive silicone gel backed by a polyester hook and loop fabric.

Indication For Use

Gelzone is indicated for use in the management of keloid and hypertrophic scars. Gelzone may also be used prophylactically to help retard the formation of such scars.

Substantial Equivalence

Gelzone is substantially equivalent to the Implantech's Gel Sheeting and Conform Sheeting cleared under 510(k) K964846 and K012419 respectively. Gelzone is also substantially equivalent to PMT's Amend™ Silicone Gel Sheeting cleared under 510(k) number K972597.

Packaging and Labeling

Gelzone will be provided in various lengths, widths and colors and packaged in a box with see through window to permit potential users to see the device prior to purchase. Use instructions along with warnings, precautions and complications are displayed on the packaging and can be easily understood and followed by OTC users. The use of this product does not require instruction by a physician to insure adequate or safe use.

Efficacy

Gelzone's silicone layer is manufactured with silicone gel. This silicone layer is the same material used in the current Implantech Gel Sheeting and Conform Sheeting products. The manufacturer of the gel has an FDA Master File which includes information on their formulation, on manufacturing methods, testing, and toxicology information.

Date: Feb 07, 2001

Stephen Meade
RA/QA Manager, Implantech Associates, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 7 2002

Mr. Stephen Meade
Regulatory Affairs/Quality Assurance Manager
Implantech Associates, Inc.
2064 Eastman Avenue, Unit 101
Ventura, California 93003

Re: K013732
Trade/Device Name: Gelzone
Regulatory Class: Unclassified
Product Code: MDA
Dated: November 5, 2001
Received: November 9, 2001

Dear Mr. Meade:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: Implantech Associates, Inc.

510(k) Number (if known): N/A*

Device Name: Gelzone

Indications For Use:

Gelzone is indicated for use in the management of keloid and hypertrophic scars. Gelzone may also be used prophylactically to help retard the formation of such scars.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013732

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-the-Counter__x____
Per 21 CFR 801.109